GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1679
ANSWERED ON:10.12.2008
COMPENSATION TO VOLUNTEERS FOR CLINICAL TRIALS
Rao Shri Kavuru Samba Siva

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the existing policy provisons to regulate clinical trials of new drugs on patients in the country allow any compensation to the volunteers, in case of any harm caused to them during the trials;

(b) if so, the details thereof;

(c) if not, whether the Government proposes to review its existing policy in this regard; and

(d) if so, the details thereof?

Answer

THE MINISTER OF STATE FOR HEALTH & FAMILY WELFARE(SMT. PANABAKA LAKSHMI)

(a) Yes sir.

(b) A clinical trial in the country has to be conducted as perthe norms prescribed under Schedule Y of Drugs and Cosmetics Act, which mandates conformance to Indian Good Clinical Practice (GCP) guidelines.The para 2.4.7. of Indian GCP guidelines prescribe provision for compensation to trial subject by sponsor in case of any harm caused to them during the trials.

(c) & (d) Questions do not arise.